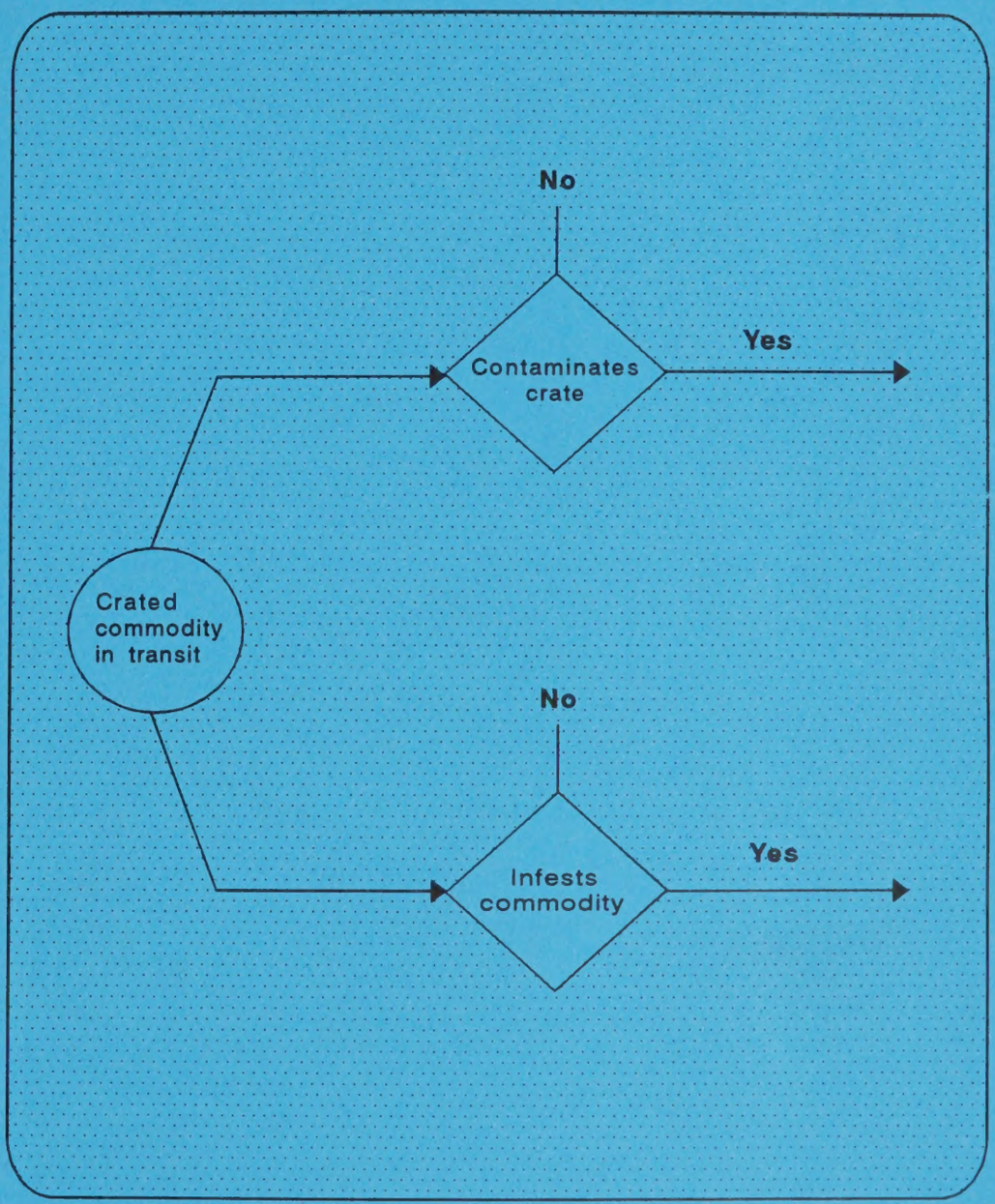
**United States Department of Agriculture**

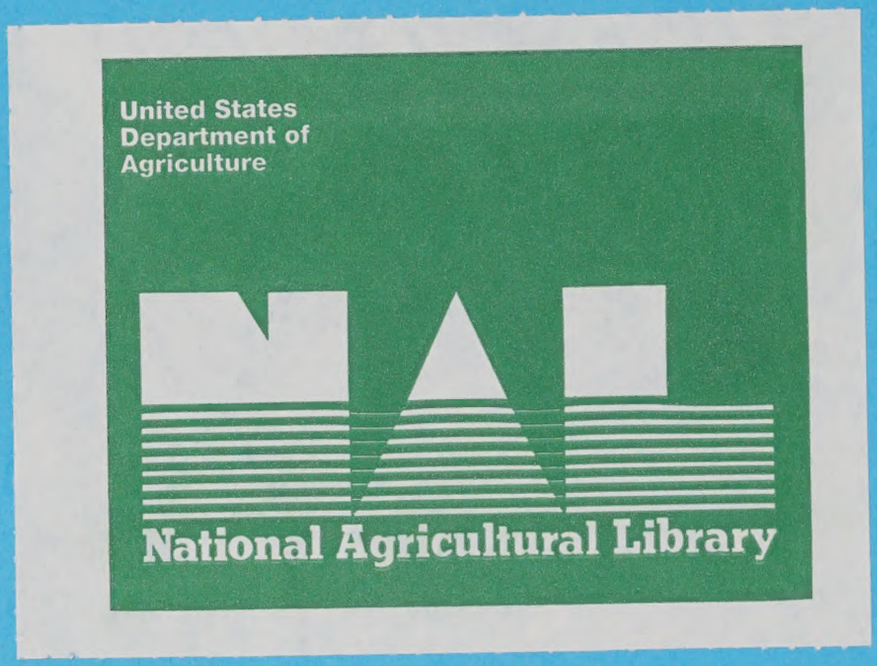
Animal and Plant Health Inspection Service

Policy and Program Development

September 1994

# What APHIS is Doing in Risk Assessment

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# What APHIS is Doing in Risk Assessment



Edited by Lorene W.H. Chang, Lynn B. Miller, Alwynelle Ahl, Michael McElvaine

# Executive Summary

**What APHIS is Doing in Risk Assessment**

Animal and Plant Health Inspection Service (APHIS) began gearing up to develop risk assessment methods and approaches in the latter part of the 1980's. In early 1994, Policy and Program Development, Planning and Risk Analysis Systems (PRAS) contacted managers, supervisors or their designees in all APHIS operations programs in which risk assessment activities were being carried out. Based on submissions from these groups about their risk assessment activities, this document, "What APHIS Is Doing In Risk Assessment" has been compiled.

Risk assessments completed in APHIS are listed along with information about access to the documents through the APHIS Library. A Risk Assessment Bulletin Board through the IDEA System, managed by Veterinary Services, Center for Epidemiology and Animal Health is explained. As risk assessments are completed in APHIS, analysts are urged to send two hard copies and one electronic copy to PRAS in order to coordinate the availability of risk assessment information through the APHIS Library and the IDEA Risk Assessment Bulletin Board.

Also APHIS' response to hazards in the past is briefly discussed. In addition, definitions for risk assessment and other terms associated with the discipline of risk analysis and environmental analysis are included.

The document shows that a wide array of tools for risk assessment are being used in APHIS, as befits an Agency with a broad mission and many programs. This document is not meant to be a final summary of approaches or methods, but a synopsis of work in progress. The goal is to stimulate and encourage discussion about risk assessment and to provide a mechanism for learning more about ongoing activities.

# Preface

Because hunting and gathering provided such an uncertain food source, our enlightened ancestors initiated the practice of agriculture some 10,000 years ago. This resulted in a more dependable dinner table and provided "leisure" time for creating the arts and sciences that underpin our civilization. Still, their food supply was anything but secure. Recurring plagues, banes, and blights ravaged herds, flocks, and fields; and people starved. Today, although enormous advances in agriculture have greatly reduced the gamble associated with food production, uncertainty still remains. Enduring the host of chance events that affect crop production continues to be a way of life for our Nation's farmers.

Since its beginning, the U.S. Department of Agriculture (USDA) has helped farmers manage these uncertainties. The Animal and Plant Health Inspection Service (APHIS) recognizes this legacy of responsibility and views the assessment and management of agricultural risks as one of its prime activities.

Because hazards to agriculture are many and varied, APHIS has analyzed risks by a variety of methods through the years. Sometimes assessments were conducted formally and the results were recorded. Often however, exigencies required that they be done quickly and informally, and no record was made of either the information used or the methods employed. Sometimes the assessments were the result of committee action, but more often they were the work of one or two persons. There were few explicit standards for this activity other than to always use good judgement, demonstrate effectiveness, and avoid risk.

But, each decade has brought its change to agriculture. The dynamic technical transformation of the nineties has affected, not only production practices, but trade conventions. The global market demands that international movement of commodities be unfettered by old restrictions. Dramatic new procedures, some at the molecular level, promise a revolution in farming. But they also present hazards that must be identified, assessed, and managed. Concern for the environment will weigh in all private and public decisions of the future. This will require improved risk assessment, management, and communication. All of these changes demand commensurate changes in our approach to risk analysis.

Fortunately, each decade has also brought its improvements to the animal and plant health sciences. Computers and other new tools can help us evaluate and analyze chance events. Modeling of complex biological systems has now become practical. Other disciplines have developed and tested novel risk assessment methods.

The Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) were among the first civilian agencies to dedicate resources to formal and documented risk analysis. They began developing and incorporating standards for this activity in the late 1970's. Within APHIS, the consolidation of resources needed to develop and standardize biological risk analysis was accomplished through the formation of the Planning and Risk Analysis Systems (PRAS) unit within the Policy and Program Development staff. This unit has the mission to "design risk assessment processes and facilitate the application of risk assessment methods" throughout our Agency.

Accordingly, in April of 1990, PRAS sponsored a 2-day conference to determine what other bio-medical agencies and institutions were doing in the area of risk assessment. At this meeting, EPA and FDA presented the approaches to risk analysis used in the regulation of exposure to hazardous chemicals and toxins. Their concern was with cumulative, non-replicating agents, especially those that might be carcinogenic. With replicating disease agents however, there was almost no concerted risk analysis effort other than that by APHIS.

Next in 1991, PRAS sponsored two meetings to determine what our international counterparts were doing in risk analysis. The first conference was held in August with our animal health colleagues on "International Seminar on Animal Import Risk Analysis (1991)." The proceedings were edited and published by APHIS. Plant health aspects were shared in October 1991 in a second conference entitled "International Approaches to Plant Pest Risk Analysis (1993)." It was jointly sponsored by APHIS and the North American Plant Pest Organization (NAPPO). The proceedings were edited by USDA and published by NAPPO.

Using information gathered from these meetings plus the expertise of selected risk analysis authorities from other fields, PRAS presented a series of workshops on risk assessment and risk communication to APHIS employees. These workshops were aimed at all levels of the organization and to interested persons in all geographical localities. As a result of these workshops, staff in many parts of APHIS began to incorporate formal risk analysis into the critical decisions of the Agency. The hazards addressed in these analyses have challenged not only agriculture but the environment, human health, and the humane care of animals. They have dealt with chemicals, residues, pathogenic agents, and the products of genetic engineering. Understandably, this diversity of adversaries has brought forth a rich variety of innovative approaches to the field of risk analysis. The narratives in this document illustrate the scope of creativity of APHIS employees. I think we will agree that our Agency is well positioned to employ risk analysis as the backbone of regulatory activity.

John A. Acree

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# Introduction

By Alwynelle S. Ahl, Planning and Risk Analysis Systems, Policy and Program Development

**Risk Assessment and Regulatory Activity**

Since the late 1970's, risk assessment has been growing in importance in Federal regulatory work. The emphasis has been on risk assessment (1) to inform risk management and risk communication activities and (2) to organize and provide expert information in the development of regulations. These trends have accelerated under the administration of President Clinton. Soon after Mr. Clinton's election, a White House Risk Assessment Reform Plan was drafted (7/2/92). The ideas in that Reform Plan were incorporated in Executive Order No. 12866 on Regulatory Planning and Review (10/4/93), which stated that regulation writing and review are to be guided by risk assessments of laws and programs. Organizational structures to oversee and implement these changes were placed in the Office of Management and Budget (OMB) and are now active. The mandate for using risk assessment in the Federal regulatory process has intensified. The goal is to assure that Federal executive resources are used where they are most needed and can do the most good.

**What APHIS Is Doing in Risk Assessment**

Animal and Plant Health Inspection Service (APHIS) began gearing up to develop risk assessment methods and approaches in the latter part of the 1980's. Examples of that activity are now illustrated in this compilation, "What APHIS Is Doing in Risk Assessment." For all the APHIS operations programs in which risk assessment activities were ongoing at the time this project was initiated, managers, supervisors or their designees were asked to respond to a series of questions (See Appendix 1). Their responses are reported here with a minimum of editing. Thus, this document was developed from responses provided by the programs of APHIS that are involved in risk assessment.

This compilation is the start of a system to share information about the continuing risk assessment activities of different APHIS groups. This activity, if kept up to date, should help prevent duplication of effort. It should be quick and easy to check and see if a similar assessment has previously been completed and what the results were at that point in time. The compilation may identify sources of data that may already have been collected as a result of a previous risk assessment which could benefit subsequent assessments. It can aid in establishing compatibilities in risk assessment approaches and results reporting throughout APHIS.

As befitting an Agency with a broad mission and many programs, there are a wide array of tools delineated for assessing risk. This document is not meant to be a final summary of approaches or methods, but a synopsis of work in progress. The goal is to stimulate and encourage discussion about risk

assessment and to provide a mechanism for learning more about ongoing activities.

**Keeping APHIS Informed**

The responses received to our request for identifying how the techniques of risk assessment are currently being employed within APHIS emphasize that our work in this area is indeed dynamic. To support this dynamic environment, Policy and Program Development, Planning and Risk Analysis Systems (PRAS) will be implementing two techniques designed to keep APHIS informed as to ongoing assessments in the future.

First, all risk assessments reported or mentioned in this book are listed in Appendix 2. Access to any assessment can be gained by calling the APHIS Library at (301) 436-5240 and requesting a particular risk assessment by its Record Number. Access may also be achieved by contacting the author or other designated contact person (See Appendix 3 for each APHIS Activity designated-contact person).

Second, in order to further promote the goal of sharing information, APHIS also is establishing, through Veterinary Services, Center for Epidemiology and Animal Health (CEAH), an electronic index to risk assessments that have been completed or are in process. This index will be part of the IDEA System (Information Dissemination Electronic Access) to which all APHIS units will have access by October 1994. The index will be updated on a regular basis by PRAS.

In order to maintain this information system on risk assessment, PRAS would like to know when your unit completes other risk assessments. Please send two hard copies and one electronic copy of the new risk assessments to

RISK ASSESSMENT DATABASE
(Michael McElvaine)
814 Federal Building
6505 Belcrest Road
Hyattsville, MD 20782

As this information is received, it will be transmitted to CEAH and the APHIS Library to maintain the system.

It is most encouraging to see the steps that APHIS has already taken with respect to the incorporation of risk assessment into its regulatory activities. We look forward to continuing progress in the use of risk assessment in APHIS.

## Defining Risk Analysis/Risk Assessment

Analysis. Assessment. Communication. Hazard. Management. Risk. All six terms have long been used in ordinary dialogue in the English language. However, these same words have been borrowed from common usage and given very specific meaning in the discipline of risk analysis.

The discipline as a formal structure of knowledge dates to the early 1950's and the military concern with "what if" scenarios of nuclear weapon use. The work of these doomsday assessors proved to have great utility in other fields. The analytical tools they developed moved quickly into the mainstream of engineering, economics, financial analysis, and the management sciences. In the early 1970's the study of risk and risk analysis was a topic of concern in management textbooks (Drucker 1993). Active Federal involvement in risk analysis began in the middle of the decade. These activities resulted in publication of a report entitled "Risk Assessment in the Federal Government: Managing the Process" (National Research Council 1983), commonly called "The Red Book." As commissioned by the Food and Drug Administration (FDA), its goal was to "strengthen the reliability and objectivity of scientific assessment that forms the basis for Federal regulatory policies applicable to carcinogens and other public health hazards." This volume provides a summary and review of early efforts to use risk analysis and assessment in regulatory review.

Thus, risk analysis is a relatively young discipline. As a consequence of that youth, the terminology used in risk analysis is in some turmoil. A glance at publications about risk analysis or attendance at national meetings of "risk" societies illustrates the difficulty of engaging in clear discussions about the topic. Vigorous arguments develop only to eventually conclude that the contenders actually agree. Different use of the language is the cause of confusion. Misunderstandings arise when workers use different words with the same or similar meanings.

In spite of current confusion, there are some national trends in the use of several words and phrases that constitute the most basic terminology of the discipline of risk analysis. These definitions and some supplementary comments are provided here.

**Risk Analysis** - the process that includes risk assessment, risk management, and risk communication.

**Risk Assessment** - the process of identifying a hazard and evaluating the risk of that hazard, whether in absolute or relative terms. It includes estimates of uncertainty and is based on the best scientific knowledge and information available.

**Hazard** - an element or event that poses potential harm, an adverse event or adverse outcome. Hazard is specified by describing what might go wrong and how that might happen. In essence, it answers the question, What can go wrong?

**Risk** - the likelihood and magnitude of the consequences of the occurrence of an adverse event, a measure of the probability of harm and the severity of the adverse effects. Risk then answers two questions: How likely is it (the hazard) to occur? How serious are the consequences if it does? The answers may be expressed in a qualitative narrative or in quantitative, probabilistic language.

The English vernacular uses "risk" synonymously with the probability of occurrence of a hazardous event or even to refer to the hazard itself. Since all of us first learned less precise uses of the word, it is not unusual to find professional risk analysts using the word "risk" idiomatically.

**Risk Communication** - open multiparty exchange of information and opinion about risk assessment leading to better understanding and better risk management decisions.

It provides a forum for exchange of information with all concerned, both inside and outside the Agency, about the nature of the hazards, the risk assessment, and how the risk should be managed. It should provide clear and unambiguous information about the outcome of risk assessment activities to those who will be affected by them.

**Risk Management** - the pragmatic decision-making process concerned with regulating risk and the consideration of appropriate measures to mitigate the risk.

Risk management can also be used to refer to policy management that encompasses the broader concern of politics, diplomacy, and international relations. It is important to recognize the context of a discussion when the term risk management is used.

Despite the utility and general use of the definitions given here, it is important to realize that the risk analysis community still has not firmly settled on a particular set of definitions. Therefore, a reader entering the territory of "risk" must carefully examine the use of terminology in context to understand the precise definition of words as used in the document at hand. In contrast, the terms used under the National Environmental Policy Act of 1969 (NEPA) are precisely defined and consistently used by proponents of the field.

## Distinctions among Risk Assessment, EIS, and Other Assessments

Under the NEPA terminology, a risk assessment is equivalent to an **environmental analysis**. Both an environmental analysis and a risk assessment evaluate the probability of occurrence of a hazard and the consequences of that hazard. However, an environmental analysis refers to the consequences of a hazard due to a proposed action whereas a risk assessment discusses consequences should the hazard occur. In NEPA terminology, an environmental analysis assesses the nature and importance of

the physical, biological, social, and economic effects of a proposed action and its reasonable alternatives. This nature and importance equate, therefore, to the "significance of the human environment." The environmental analysis allows for informed decisions to be made about the consequences of a proposed action. If appropriate, a risk assessment or an environmental analysis becomes the analytical part of an environmental assessment.

An **environmental assessment** is a public document that presents the results of an environmental analysis and discloses the environmental consequences of the proposed action. The purpose of an environmental assessment is to provide sufficient evidence and analysis for determining whether to prepare an *Environmental Impact Statement* (EIS) or a *Finding Of No Significant Impact* (FONSI) on the human environment.

An EIS functions as a public device to insure that the spirit of NEPA is infused into the actions and programs of the Federal government. An EIS shall: be analytical and concise; have a range of alternatives discussed that are reasonable and encompass those to be considered by the decisionmaker; state how alternatives considered in it and decisions based on it will or will not achieve the requirements of NEPA or other environmental laws or policies; and serve as the means of assessing the environmental impact of the proposed agency action, not a justification of a decision already made.

In accordance with the Endangered Species Act (ESA), all Federal agencies shall ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of an endangered or threatened species (E/T) or result in the destruction or adverse modification of habitat determined to be critical. A **biological assessment** is an analytical document that evaluates the potential impacts of the Federal action on an E/T or its habitat. In order to determine whether an activity may affect an E/T species or its habitat, a Federal agency shall prepare a biological assessment. This may be done in conjunction with the preparation of an environmental assessment or an EIS. If the Federal agency determines through its biological assessment that the proposed activity "may affect" any E/T species or the species' habitat, the Federal agency is required to consult with the Fish and Wildlife Service (FWS). This consultation may be formal or informal and may be initiated by the submission of the Federal agency's biological assessment to the FWS, along with a request for consultation. The preparation of a NEPA document alone does not relieve a Federal agency of its requirements under the ESA unless the E/T evaluation included in the NEPA document sufficiently analyzes the impacts of the proposed action on the species and its habitat. The NEPA document may then suffice for a biological assessment and may be used in consultation with the FWS if it is determined that the proposed action "may affect" E/T species or critical habitat.

(Thanks to APHIS colleagues in Environmental Analysis and Documentation of Biotechnology, Biologics, and Environmental Protection for providing the information contained in this section.)

**References**

Clinton, W.J. Executive order No. 12866: Regulatory planning and review, October 4, 1993.

Drucker, P.F. The manager and the management sciences in management: tasks, responsibilities, practices. New York: Harper & Row, Publishers, Inc.; 1993.

Gay, C.G.; Orr, R.L. Risk analysis for veterinary biologics. [Hyattsville, MD]: Biotechnology Section, Veterinary Biologics; Biotechnology, Biologics, and Environmental Protection; Animal and Plant Health Inspection Service; U.S. Department of Agriculture; 1994.

National Research Council. Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences. Risk assessment in the Federal Government: managing the process (also known as "The Red Book"). Washington, DC: National Academy Press; 1983.

U.S. Department of Agriculture, Animal and Plant Health Inspection Service. Strategic plan: meeting producer and public needs. [Hyattsville, MD]: U.S. Department of Agriculture, Animal and Plant Health Inspection Service; 1989.

# General

## Animal and Plant Pest Risk Assessment and Information Systems: APPRAIS

By Lynn Miller, Planning and Risk Analysis Systems, Policy and Program Development

**Why are you doing risk assessments?**

The primary purpose of the Planning and Risk Analysis Systems (PRAS) staff is to develop and test new risk assessment methods. This testing and development may include building computer software programs to support new information and risk assessment systems, as described above. PRAS is supporting the development of a number of separate software applications dedicated to both plant and animal health issues, which collectively make up Animal and Plant Pest Risk Assessment and Information Systems (APPRAIS). The applications currently under development include:

- Brucellosis Epidemiologic Simulation Model (BRUSIM), which measures the impact of changes in major U.S. bovine brucellosis program components

- Import Risk Information System (IRIS), an automated quantitative risk assessment system that supports the development of a scenario tree, an evidence database, and calculates risk estimates using probability distributions to accommodate uncertainty in parameter estimates

- Plant Pest Risk Information System (PPRIS), an automated system to help identify, assess, and manage exotic and emerging organisms that may pose a risk to plant resources

Other applications in the planning stages include the development of Geographic Information Systems (GIS), and an electronic bulletin board listing ongoing Animal and Plant Health Inspection Service (APHIS) risk assessment activities.

Methods developed and currently used, include the Generic Process (Orr, Cohen, Griffin 1993), Enhanced Hazard Identification Process (Richard Orr, Robert Griffin), Scenario Tree Analysis (Ahl and Orr 1991), and Risk Mitigation Matrix Analysis (Orr, Cohen, Griffin 1993), and the nested binomial (Victor C. Beal, Jr.).

In addition to this systems development work, the PRAS staff works directly with operational staffs to test applications of risk assessment techniques by conducting actual risk assessments and providing program managers with risk assessment information to support better decision making.

**How often do you do risk assessments?**

Typically, PRAS provides technical assistance in complex, long-term risk assessments, many of which are actually conducted by the specific subject-matter expert from an operational staff. PRAS involvement in risk assessment is continuous, covering a variety of topics and issues.

**What methods or models do you use in completing risk assessments?**

In conducting qualitative risk assessments, the Enhanced Hazard Identification and/or Generic Process are most commonly used. In quantitative risk assessments, use of the nested binomial and probability density function are used, depending on the level of information available and the type of risk questions asked. For both qualitative and quantitative assessments, use of a scenario tree model is common to outline the steps or phases of the program operations under assessment. Frequently, an assessment incorporates multiple methods and may have both quantitative and qualitative sections.

**How are risk assessments being used?**

Risk assessments are being used by the PRAS staff to test new methods, and new applications of previously developed methods. These same risk assessments may be used by the originating staff to direct program activities, set policy, or make immediate decisions on permit applications.

**How do you envision that risk assessment as a process will be used in APHIS 10-20 years from now?**

I believe that most risk assessment activities will be automated, which will allow:

- Some standardization of methods
- More efficient use of resources, including analysts, information, and expertise
- Easier sharing of risk information, especially as the assessment is being conducted
- Greater reliance on electronic access to and transfer of biological and geographic information

I believe risk assessment will support a wide variety of methods and applications, with heavy emphasis on resource management and risks associated with economic/legal issues, in addition to our current focus on biological risk assessments. Risk assessment activities will more often be used to provide valuable information for decision makers to consider while formulating long term policy.

## Developing Plant Pest Risk Assessment and Information Methods

By Sue Cohen, Planning and Risk Analysis Systems, Policy and Program Development

**Why are you doing risk assessments?**

My primary focus is to develop new plant pest risk assessment and information methodology. Specific plant pest examples are provided by Biological Assessment and Technical Support or Domestic and Emergency Operations, Port Operations, in Plant Protection and Quarantine (PPQ) for testing of new plant pest risk assessment and information methodology. I have been involved in developing the Generic Non-Indigenous Pest Risk Assessment Process. This process has been tested with various timber and single pest issues (See Appendix 2, General or Methodology section). Development of these risk assessment and information tools is in direct support of other Animal and Plant Health Inspection Service (APHIS) staff needs and fulfills APHIS' Strategic Plans for Risk Analysis.

**How often do you do risk assessments?**

Risk assessments are only needed for testing of new processes and take up 30 percent of my time. Most of my time is spent developing and revising risk processes. APHIS program staffs are responsible for writing and compiling the actual risk assessments.

**What methods or models do you use in completing risk assessments?**

Data is evaluated, and the best method selected for the particular data set. Methods I have used are the Generic Process (See Appendix 2, Plant Protection: Generic Process), Risk Information Systems, and Geographic Information Systems (See Appendix 2, Wildlife Management).

**How are the risk assessments being used?**

The New Pest Advisory Committee and the PPQ domestic operations staff have used some to make decisions. Other APHIS staffs and Forest Service have used some to make pest management decisions.

**How do you envision that risk assessment as a process will be used in APHIS 10-20 years from now?**

I believe a giant data bank will exist with information on all biological organisms and ecosystems fueled by the National Biological Survey and European Diversity Database. Data will be accessed by the Information Superhighway. More information will be known, as well as environmental effects. There will be less uncertainty in the data. However, there will always be a need for a documented decision process. Impacts on ecosystems will be added to the decision process. Risk analysis will not always be quantitative because data will not be available or it will be too costly to obtain the necessary data. Data will also be geo-referenced.

## Risk Assessments in Policy Analysis and Development, Policy and Program Development

By Trang Vo, Policy Analysis and Development (PAD), Policy and Program Development

**Why is PAD doing risk assessments?**

Economic analysis is an important component of the resolution of many of Animal and Plant Health Inspection Service's (Agency or APHIS) issues dealing with pest and disease management. One of Policy Analysis and Development's (PAD) primary responsibilities is to provide advice and analyses on proposed economic studies, especially those leading to policy decisions for the Agency. Such studies might include, for example, economic components of Environmental Impact Statements (EIS), benefit-cost analyses of foreign and domestic pest management programs, and regulatory impact analyses of proposed Agency actions. In a sense, these studies are analyses of *economic risk* in that they are conducted to determine the probable impact of pest and disease introduction, control strategies and policy actions on the economic environment.

**How often does PAD do risk assessments?**

Economic risk assessments are conducted continuously. The length of time spent on each analysis depends on the type of assessment, available data, and related methodologies. Most typical regulatory impact analyses that the Agency prepares in compliance with executive orders and legislative mandates require from a few days to a few weeks to complete. Other more complex studies such as regulatory impact analyses of proposed regulations that are deemed potentially significant, and economic components of EIS's, can require from 6 months to over 1 year to complete.

**What methods are used in economic risk assessments?**

For the majority of issues confronting APHIS, information is often needed on actual and potential economic losses from pests and diseases, and on the benefits and costs of pest and disease management. Economic analysis of these costs and benefits, and of the design of control policies to mitigate pest and disease damage, falls within the domain of *welfare economics*. A basic concept used in welfare economics is that the change in an individual's economic well-being due to an event can be measured in terms of the individuals's willingness to pay to obtain the event (if it is a "good") or to avoid it (if it is a "bad"). If all individuals in society are categorized as consumers and producers, then changes in social welfare can be analyzed in terms of markets.

The measurement of potential economic consequences are refined by incorporating biological risks of the pest or disease in question. Biological risk assessments are typically conducted to identify either the level of risk presented by various regulatory activities or high risk pathways for the introduction of pest and disease. These assessments are conducted by the

specific subject-matter expert from an operational staff, oftentimes with statistical collaboration from the Planning and Risk Analysis Systems (PRAS) staff. The estimated biological risk utilizes both quantitative and qualitative methods that are elsewhere discussed in this document. Biological risks in the form of probability estimates signifying the likelihood of disease/pest introduction are then used to determine the expected value of losses and benefits of a pest or disease introduction and their control alternatives.

**How are the risk assessments being used?**

The basic aim of PAD's economic risk assessment is to aid decision making by quantifying those benefits and costs of APHIS programs that can be quantified, and by ranking those factors that are nonquantifiable. Economic risk assessments are used to support regulatory proposals to comply with legislative mandates and executive orders governing rulemaking. They are also used to support decision making in several forms: by guiding the allocation of program resources to address alternative pest and disease management tools, and by assisting policy makers in balancing regulatory activities with the commensurate risks associated with various pests and diseases.

**Do you have a list of risk assessments produced in your APHIS work?**

Samples of some recent, major economic risk assessment studies conducted in PAD are listed in Appendix 2 under their respective categories.

# Animal Protection

## Risk Assessment at the Center for Emerging Issues (CEI): Centers for Epidemiology and Animal Health

By Anita Bleem, Center for Emerging Issues, Centers for Epidemiology and Animal Health, Veterinary Services

**Why does CEI do risk assessments?**

Most of the risk assessments that the Center for Emerging Issues (CEI) has conducted are the result of direct requests from Animal and Plant Health Inspection Service (APHIS) and/or Veterinary Services management. Our assessments have included a broad, big picture perspective of the issue with an evaluation of animal and human health risks. A few assessments have been done based on our perceived need of coverage and clarification of an issue. Such assessments are approved by Hyattsville management.

**How often do you do risk assessments?**

Our risk assessments tend to be 6 to 9-month-long projects and take approximately 75 percent of staff time in a given year. During critical phases of the assessment, it is not uncommon for most staff to commit 90 percent or more of his/her time to the project.

**What methods or models do you use in completing risk assessments?**

The models and methods used vary according to the project. We have used both quantitative and qualitative approaches in our assessments, with the latter used more frequently. We rarely have the necessary data to do detailed statistical modeling. The lack of numerical data results in assessments that are often descriptive in nature with a heavy reliance on graphical representation to display concepts.

**How are risk assessments being used?**

Policy and industry leaders are the primary beneficiaries and users of our risk assessments. Our conclusions assist them in making decisions, establishing policy, and improving animal and human health. Our interpretations often suggest the need for further research into critical areas.

**How do you envision risk assessment as a process that will be used in APHIS 10-20 years from now?**

Because the public is increasingly critical of the Nation's food supply and any risks therein, APHIS will continue to rely heavily on risk assessment, especially in the food safety arena. As long as consumers demand safer products, well-conducted, easy-to-understand risk assessments should be an APHIS priority.

## Risk Assessment Activities with the Import/Export Staff of Veterinary Services

By Richard Fite, Planning and Risk Analysis Systems, Policy and Program Development

**Why are you doing risk assessments?**

I am currently working with Veterinary Services, National Center for Import and Export staff to do risk assessments on issues of current interest. My purpose in doing this is threefold:

- Demonstrate simple, transparent, scientific, quantitative methods for doing risk assessments that the import/export staff can use in their own work
- Embed risk assessment in the policy making procedures in Animal and Plant Health Inspection Service
- Increase my own skill in performing risk assessments

**How often do you do risk assessments?**

This activity occupies about 50 percent of my professional time.

**What methods or models do you use in completing risk assessments?**

Risk assessments are completed using scenario trees, evidence lists, and split fractions for probabilities. Uncertainty is handled with either point estimates, range estimates, or probability distribution functions.

**How are the risk assessments being used?**

These risk assessments are available to decision makers when formulating new import/export policies, or changing existing policies.

## Risk Analysis Activities: National Center for Import and Export

By Robert F. Kahrs, National Center for Import and Export, Veterinary Services

**Why are you doing risk assessments?**

Staff of the National Center for Import and Export conduct about 10,000 risk assessments annually to assist specific import decisions, to underpin promulgation of import-export regulations, to recommend specific procedures for regulatory oversight of import-export activities designed to protect U.S. livestock, poultry, and wildlife populations from exotic diseases, and to maintain and expand markets abroad by assuring exported commodities meet the animal health requirements of recipient nations.

**How often do you do risk assessments?**

Written, extensively detailed quantitative or semi-quantitative risk assessments are conducted in consultation with import-export and other Animal and Plant Health Inspection Service (APHIS) Staff by a self-directed work group comprised of a mathematical statistician and two veterinarians trained in risk evaluations. They devote 1.6 man-years to risk assessment. These documents include probabilistic risk statements under various mitigating circumstances and recommendations as to their acceptability.

**What methods or models do you use in completing risk assessments?**

The level of sophistication and methodologies of these risk assessments run the gamut from gut reactions and educated guesses to extensive detailed quantitative evaluations of both the risks and the potential consequences associated with importing commodities from specific regions of the world.

Qualitative risk assessments are based upon collective experience and background of staff, their knowledge of transmission and global distribution of animal diseases, their subjective assessment of the final destination and point-of-origin health certifications, and postentry restrictions. Summaries of these subjective assessments are reported verbally or spelled out on permits or correspondence.

The documentation attached to each detailed quantitative risk statement specifies the methodology and mathematical models employed. It states the assumptions used to ascertain probabilities of various outcomes and makes citations to the scientific and professional literature. Methodologies most appropriate to each situation are chosen. They include use of triple-binomial and scenario models and may employ "At Risk" software package or spreadsheet methods.

**How are the risk assessments being used?**

Although some are done to assess hazards of exportations, the majority of qualitative subjective assessments respond to requests for import permits for products, organisms or vectors, birds, poultry, and animals. The majority of quantitative assessments are undertaken to evaluate proposed regulations or to evaluate major imports that are economically or politically sensitive or that need reevaluation due to advancing technology or changing global distribution of disease-producing agents.

## Risk Assessment in REAC: Animal Care Risk-Based Resource Allocation Project

By Michael McElvaine, Planning and Risk Analysis Systems, Policy and Program Development. Through: Dale Schwindaman, Deputy Director, Regulatory Enforcement and Animal Care

**Why are you doing risk assessments?**

In July 1993, Dr. Dale Schwindaman, Deputy Administrator of Regulatory Enforcement and Animal Care (REAC) requested the help of Planning and Risk Assessment Systems (PRAS) to look at applying risk assessment methods to resource allocation in the Animal Care (AC) program. PRAS accepted the invitation and agreed to a developmental project looking specifically at the resources used for research facility inspection.

Resource allocation is a critical part of any program, especially in times of budget and personnel cuts. The AC program is also facing increased program demands at the same time they are facing the current budgetary crunch. PRAS agreed to this developmental project to explore the application of risk-based decision making in a different context from our previous projects. If this project succeeds, the results can be used by the REAC management team to guide future policy and program decisions.

Since this is an ongoing project, I can only report in generalities about goals and plans. And, since this is a developmental project, none of this work should be considered as official policy of the AC program at this time. At the conclusion of the project, the AC management will review the results of the project and decide whether to adopt any of the recommendations.

## Veterinary Services' Central Regional Epidemiologist Risk Assessment Activities

By Mark A. Schoenbaum, Regional Epidemiology Officer, Central Region, Veterinary Services

**Why are you doing risk assessments?**

I consider these evaluations important because they document and justify regulatory action. I conduct these evaluations when other regulatory veterinarians want to know the odds or predict the outcome of some intervention (or lack thereof).

**How often do you do risk assessments?**

I probably do three to eight such studies each year.

**How do you envision risk assessment as a process will be used in APHIS 10-20 years from now?**

I expect that risk assessments will pay an increasing role in future decisions in the agency.

**Do you have a list of risk assessments produced in your APHIS work?**

I am enclosing two samples of my analyses during the last 8 months. One is a summary of using a model (Schoenbaum 1993b) that I developed for surveillance systems, in this case pseudorabies. This model can be used to answer a variety of questions. The second example of my risk evaluations involves the diagnosis of tuberculosis (or freedom of tuberculosis) in one dairy in Texas (Schoenbaum 1993a). Subsequent to this assessment, the dairy was determined to be infected based on the post-mortem examination of the first six animals.

# Environmental Protection

## Risk Assessment at Environmental Analysis and Documentation

By Jack Edmundson; Environmental Analysis and Documentation; Biotechnology, Biologics, and Environmental Protection

**Why are you doing risk assessments?**

Environmental Analysis and Documentation (EAD) is involved in the writing of environmental impact statements (EIS's) that Animal and Plant Health Inspection Service (APHIS) prepares in compliance with the National Environmental Policy Act (NEPA). As part of the NEPA process, we are charged with providing an analysis of the potential for projects to result in impact to the human environment. In a sense, therefore, all EIS's are risk assessments. In a more strict sense, however, we have only prepared a few risk assessments (See below) under NEPA. We also perform Biological Assessments (BA's) as part of our compliance with the Endangered Species Act (ESA). These are essentially risk assessments to determine potential impact of projects on endangered and threatened species.

**How often do you prepare risk assessments?**

Every project that receives NEPA analysis has some sort of risk analysis associated with it, although only a few have actually resulted in documents called risk assessments.

**What methods or models are used?**

We follow no standard method, per se. Since every project is distinct, we look at them all individually. As for a model, we basically try to break our risk assessments into three parts: an analysis of hazard, an analysis of exposure, and then an analysis of risk.

**How are the risk assessments being used?**

They are used to support our compliance with NEPA and ESA. They can also be used to provide the programs with ways to mitigate undesirable impacts of projects and to help design more effective projects.

**How do you envision that risk assessment as a process will be used in APHIS 10-20 years from now?**

The risk assessment process as we know it is a logical way to design programs so as to minimize undesirable effects. Because of the growing controversies surrounding APHIS programs, it will probably also provide supportive documentation that will be essential to garnering public support.

**Do you have a list of risk assessments produced in your APHIS work?**

Strictly speaking, we have prepared two official risk assessments. Both were associated with the Medfly EIS. One was for human health and the other for nontarget organisms. We are also currently involved in preparing an ecological risk assessment and a human health risk assessment to support the gypsy moth EIS that APHIS and the Forest Service are preparing. Depending upon your definitions of risk assessment, we also have lists of all the NEPA documents and BA's we have done.

## Risk Analysis for Veterinary Biologics: Biotechnology, Biologics, and Environmental Protection

By Cyril Gay; Veterinary Biologics, Biotechnology Section; Biotechnology, Biologics, and Environmental Protection

**Why are you doing risk assessments?**

The Veterinary Biologics (VB) risk analysis process is used to ensure the safety of new experimental veterinary biologics. It is a multi-factorial approach to risk assessment; risk to animals, public health, and the environment are assessed. The risk analysis process includes a risk assessment, risk management recommendations, and procedures for communicating risk. The standard definition of risk is used: the likelihood of an adverse event occurring and the consequences if that adverse event occurs. A comprehensive scientific analysis, peer review, public notification, and documentation of the decision-making process are required. This approach is consistent with accepted standards for conducting risk analysis (Cohrssen and Covello 1989, National Research Council 1983, 1992).

The risk analysis for VB centers on the safety characteristics of the vaccine microorganism and the environment in which the research is to be performed. The safety characteristics of the vaccine microorganism are based on specific empirical data and established scientific information. This information is provided by the applicant when completing the appropriate VB Summary Information Format (SIF) (Gay and Roth 1994).

**How often do you do risk assessments?**

As of April 22, 1994, VB has performed 28 risk analyses.

**What methods or models do you use in completing risk assessments?**

The risk approach developed for VB is a hybrid of various risk outlines taken from the risk assessment literature, workshops, and risk projects relating to non-indigenous organisms. Foremost among these were the U.S. Council on Environmental Quality guide to principles and methods for analyzing health and environmental risks (Cohrssen and Covello 1989), the National Research Council (1992) workshops and meetings for the development of ecological risk assessments, and the thesis by Levin and Straus (1991) on risk assessment in genetic engineering. The basic approach and philosophy used by VB in the development of the VB risk analysis process borrows significantly from these sources.

For a more indepth look at the model used by VB, see "Risk Analysis for Veterinary Biologics" by Gay and Orr (1994) (See Appendix 2 under General or Methodology.).

**How are the risk assessments being used?**

The risk analysis for VB is used to (1) determine whether a request to ship an experimental veterinary biologic should be approved or denied, (2) ascertain whether adequate information was provided with the request, (3) provide appropriate mitigative recommendations to reduce or eliminate potential safety risks, (4) prepare National Environmental Policy Act (NEPA) environmental documents, and (5) communicate the risk and/or level of uncertainty associated with the proposed request to the concerned public. The objective is to ensure the safety of experimental veterinary biologics. One important feature of this risk analysis is that significant effort is placed on the identification of hazards early in the risk analysis process. This is accomplished by providing industry with VB SIF's in the early stages of product development.

The risk assessment conducted by VB is a judgmental process based on the best available science. The risk assessment includes the identification of safety hazards, a release assessment, and the characterization of safety risks to animals, public health, and the environment. It is used to determine whether risks are associated with the specific proposal to test and/or release an experimental veterinary biologic from containment, and to characterize the degree of uncertainty associated with the proposal.

**Do you have a list of risk assessments produced in your APHIS work?**

Three risk analyses that have had the confidential business information removed and a summary of the risk assessment process are available for review (See Appendix 2 for a complete reference to the respective articles: Animal Protection - Biotechnology Section, Veterinary Biologics 1994a, b, and c; General or Methodology - Gay and Orr 1994).

**References**

Cohrssen, J.J.; Covello, V.T. Risk analysis: a guide to principles and methods for analyzing health and environmental risks. U.S. Council on Environmental Quality, Executive Office of the President; 1989.

Gay, C.G.; Roth, H.J. Confirming the safety characteristics of recombinant vectors used in veterinary medicine: a regulatory perspective. Dev. Biol. Stand. 82: 89-101; 1994.

Levin, M.A.; Strauss, H.S. Risk assessment in genetic engineering. U.S. Council on Environmental Quality, Executive Office of the President. 1991.

National Research Council (NRC). Risk assessment in the Federal Government: managing the process. Washington DC: National Academy Press; 1983.

___. Issues in risk assessment. Washington DC: National Academy Press; 1992.

## Risk Assessment for Biotechnology Permits

By David Heron; Biotechnology Permits; Biotechnology, Biologics and Environmental Protection

**Why are you doing assessments?**

As part of its risk assessment activities, Biotechnology Permits (BP) prepares environmental assessments (EA's) in compliance with the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA). Under the provisions of NEPA, Federal agencies are required to assess the potential impacts resulting to the environment as a consequence of the activities that meet the NEPA definition of a "major Federal action." BP conducts environmental analyses and prepares environmental assessments in conjunction with two of its primary responsibilities: (1) issuing permits for field tests of genetically engineered plants and microbes and (2) determining that certain genetically engineered plants will no longer be considered as "regulated articles" under Animal and Plant Health Inspection Service (APHIS) regulations found at 7 CFR Part 340.

**How often do you prepare risk assessments?**

Since 1987, BP has prepared over 400 EA's prior to issuing permits to conduct field tests with genetically engineered plants and microorganisms that are considered "regulated articles." When the permitting program began, EA's were prepared before issuing all permits. Subsequently, EA's have been prepared when previous analyses have not adequately addressed the unique aspects of a proposed field test (e.g., test site in a different state, different species of test organism, or different genes inserted into the organism).

After conducting a field test to confirm that a genetically engineered plant exhibits the desired agronomic attributes, individuals can submit a petition requesting that BBEP make a determination that the plant no longer needs to be a regulated article under 7 CFR Part 340. Before making such a determination, data from the petitioner and the scientific literature are reviewed, and an environmental assessment is prepared.

**What methods or models are used?**

We do not use any specific model. Our assessments are tailored on a case-by-case basis to focus on the genetic modification, the plant, and the environment in which the genetically engineered plant will grow.

**How are the risk assessments being used?**

The assessments are used as part of our compliance with NEPA and ESA. The assessments also guide our decisions and provide information to the public when BP issues field test permits or determines that a transgenic plant no longer needs to be considered as a regulated article under APHIS regulations (7 CFR Part 340).

**How do you envision that risk assessment as a process will be used in APHIS 10-20 years from now?**

Assessments prepared by BP in the future probably will continue to be an important way to provide information to the public about the potential impacts associated with the new developments in plant biotechnology. Conceivably, assessments will increasingly be used if genetically engineered microorganisms are developed for bioremediation or biological control purposes. The technological successes over the past few years will likely lead to even greater exploration of genetic engineering to improve agriculture.

**Do you have a list of risk assessments produced in your APHIS work?**

Yes, BP maintains copies of past risk assessments and makes them available to the public, either as "hard copies" or in electronic format. In addition, BP maintains an electronic database that is available to the public. The database includes information on the types of genetically engineered plants that have been field tested under APHIS authority.

# Plant Protection

## Risk Assessment in PPQ'S Biological Assessment and Taxonomic Support

By Ed Imai, Biological Assessment and Taxonomic Support, Plant Protection and Quarantine

**Why are you doing risk assessments?**

To support decision making by Biological Assessment and Taxonomic Support (BATS) and other staffs of Plant Protection and Quarantine (PPQ) and International Services. The risk assessments are performed by completing Decision Sheets submitted by the Permit Unit for fruits and vegetables, or by memo on other plants and plant products.

**How often do you do risk assessments?**

The Commodity Pest Risk Analysis Branch of BATS works full time to determine pest risk and evaluate pest mitigation measures for commodities imported, transiting, and exported from the United States.

**What methods or models do you use in completing risk assessments?**

The most frequent model used is the Decision Sheet (PPQ Form 348). The decision sheet is supported by the use of attachments - an attachment for arthropods and an attachment for pathogens. Copies of supporting documents, such as literature, memos, correspondence, or bilateral minutes may be enclosed with the decision sheets. A modified decision-sheet process was used to assess the risk on a regional basis. An example of a regional Pest Risk Assessment (PRA) was for cilantro from El Salvador, Honduras, and Nicaragua. The recommendation was to allow cilantro to enter the United States from all Central American countries.

The other model is a PRA for a specific pest. This model was used for the cherry ermine moth, *Yponomeuta padella* (See appendix 2, Plant Protection: Chawkat 1994).

The third model is a PRA for a geographic region. This model was created to assess the risk of establishing a treatment facility in geographic regions where host plants of pests may be available and the environmental conditions may be favorable for establishment.

The fourth model is a PRA for a commodity. An example is the PRA for New Zealand corn seeds (See appendix 2, Plant Protection: Redlin 1992).

Many PRA's are developed on demand and documented as decision memos/papers. Examples are bilateral discussions, ad hoc queries and requests, pest interceptions, pre-clearance issues, work plans, and others.

**How are risk assessments being used?**

The decision sheet is used for immediate decision making to issue or deny a plant products import permit. The pest and geographic region PRA's are for policy guidance and the development of program priorities.

**How do you envision that risk assessment as a process will be used in APHIS 10-20 years from now?**

The PRA's will become more transparent. The process will change from importing countries doing PRA's on imports, to the exporting countries (as a means to support exports) doing PRA's for review by the importing country. There will be more cooperation/joint PRA's among countries and exchange of information to standardize the PRA process. An example is our current exchange of information with Canada.

BATS is developing pest lists for U.S. export products for Australia, New Zealand, and China. Chile has sent us a list of pests of quarantine concern to them, and the United States is providing information to mitigate the risk on the pests of concern to Chile.

BATS is reviewing data from Chile and Korea on the systems approach to mitigate risk. For Chile, the systems approach will allow true potato seeds from certified fields to enter the United States. Korea is working on a systems approach to allow the export of apples to the United States without treatment.

**Do you have a list of risk assessments produced in your APHIS work?**

See the article by Robert Griffin. In addition, a list of current PRA's is available from BATS.

## Collaborative Risk Assessment Activities: Biological Assessment and Taxonomic Support and Planning and Risk Analysis Systems

By Robert Griffin, Planning and Risk Analysis Systems Staff, Policy and Program Development

**Why are you doing risk assessments?**

The objective of most of my work is to bring conceptual risk assessment into an operational realm, primarily for plant quarantine. I do this by first learning about new methodologies and extracting ideas from risk assessment in other disciplines and then testing different ideas on real-world problems. Some of this I do independently, but most is done in conjunction with the personnel responsible for programmatic risk assessments.

**How often do you do risk assessments?**

My time is fairly evenly divided between training myself in risk assessment and working with others on risk assessments or on understanding and using risk assessment concepts to advantage in program decision-making. I rarely do a risk assessment independently, but I normally work on three or more at a time with others. A large portion of my time involves reviewing program activities, policies, and regulations and providing input concerning ways to view, measure, and adjust their risk basis.

**What methods or models do you use?**

I attempt to utilize any and all tools available to me for risk assessment. While the concepts behind the work are fairly consistent, I find that no single approach is adequate for all situations. I begin by weighing the data against the expected product, the time and resources available, and the methodologies that might be useful. I find that there are many situations when, for various reasons, it is "a given" that certain risks will be accepted, but it is important to identify the most important risks and a factor (or factors) that will mitigate that risk to a level the program managers, industry, or the public will be more comfortable accepting. A ranking process such as Enhanced Hazard Identification combined with a Hazard Analysis Critical Control Point (HACCP) process seems to work well in support of a very large number of plant quarantine risk-based decision needs. I hope to test this further and possibly redefine possibilities for the marriage of these two processes.

**How are risk assessments being used?**

Risk assessment is most commonly thought of as a tool to be used for organizing information in order to support risk-based decision making. However, risk assessment also holds as its basis a number of important concepts that need to be understood and incorporated into the routine thought processes of program personnel. The products and outcomes of my work are as much associated with "the document" representing a risk assessment as they are with simply working side-by-side with program

personnel in an effort to identify some invalid or ineffective paradigms and to develop better alternatives. In all instances, the focus of my work is in developing the best risk-basis for program decision-making.

**How do you envision that risk assessment as a process will be used in APHIS 10-20 years from now?**

I believe we are in an awkward period of transition, the adolescence of our institutional growth where risk assessment is concerned. Once some historical baggage has been shed and traditional thoughts become more contemporary, I believe we will see a new generation of regulatory personnel with a much more sophisticated and holistic view of risk assessment. I predict that it will eventually become a routine activity that is recognized as the heart of mainstream decision making, but it will be taken for granted as a normal part of our activities and thought processes. Hopefully, there will be less emphasis on a special technique or a special staff or any of the artificial barriers that bureaucracies tend to create.

**Do you have a list of risk assessments produced in your APHIS work?**

I do not (at this time) have a list of risk assessments. However, I do have documents that could be provided to anyone with an interest. In addition, as mentioned above, I also have (and continue to have) valuable experiences related to the real-world interface between "the way things work" and "the way things might work better." While largely undocumented, and constantly evolving, I believe that this experience and understanding could be an important asset that may also be tapped.

## Development and Application of Plant Pest Risk Assessment Methods

By Ed Miller, Planning and Risk Analysis Systems Staff, Policy and Program Development

**Why are you doing risk assessments?**

My purpose in doing risk assessment is twofold. First, it is to develop useful methodologies, and secondly to expose Animal and Plant Health Inspection Service (APHIS) operational and staff personnel to a range of risk assessment techniques in order to assess their usefulness within APHIS.

**How often do you do risk assessments?**

Approximately 50 percent of my time is spent working on risk assessments. In addition, about 25 percent more of my time is spent on other risk assessment activities, including training, reading, reviewing other assessments, and discussions.

**What methods or models do you use in completing risk assessments?**

The methods, models, and purposes have varied with each assessment, as explained in the following paragraphs.

**Qualitatitive Risk Assessment**

For the Mediterranean Fruit Fly risk assessment (See appendix 2, Plant Protection: Miller 1992), the basic approach was qualitative, although a large section was quantitative. The major purpose of the assessment was to identify the high risk pathways for this serious pest. All possible pathways for this pest were evaluated, and assigned a high, moderate, or low risk rating. This rating was subjectively assigned by the primary assessor after the review of all pertinent evidence. The evidence included published literature, APHIS reports, pest interception reports, an onsite review of port activities, and meetings with subject matter experts. Risk management recommendations were developed and included in the document.

One of the major purposes of this assessment was to show the scope and depth that a pathway study can have if given sufficient resources. This assessment has been used:

- As a decision-making device; a number of its recommendations have been implemented and others are still under consideration
- For a general reference both within APHIS and for our trading partners
- To stimulate research in DNA fingerprinting to support the development of better risk estimates in order to refine quantitative analysis

**Quantitative Risk Assessment**

Three projects, the Sharwil Avocado Risk Analysis (July 1991), the Port of El Paso Risk Assessment (in progress), and the Fruit Fly Eradication Program Risk Analysis (in progress) are similar in approach. These projects share the following characteristics:

- Purpose - to estimate the risk of various elements of a program or activity so that risk managers can better determine how to use their resources
- Use of scenario analysis; i.e., the development of a short model or event tree, and the identification of pertinent parameters
- Use of a probability distribution to indicate uncertainty
- Derivation of parameter estimates based on the elicitation of expert information
- Use of the hazard identification process as a formal part of the risk assessment

The Sharwil Avocado Risk Analysis was completed by the use of an expert group made up of a cross section of people, including researchers and regulatory plant health specialists. Using the risk estimates generated from the expert group, a second meeting was held to develop a set of operational recommendations for program managers. The complete assessment took approximately 2.5 months (See Miller 1991 in appendix 2, Plant Protection).

The objective of the Port of El Paso Risk Assessment is to determine the risk from exotic pests associated with the movement into the United States of people, vehicles, and cargo at a Plant Protection and Quarantine (PPQ) port of arrival. It will be an assessment only, with no risk management element included. It is intended to enable various people within APHIS (port personnel, port managers, regional managers, and headquarters staff) to better understand and manage risk at U.S. ports. This is a large, complex project which will take about 3 years to complete. Several assessors from a variety of backgrounds have used a number of separate expert groups to help develop the risk estimates used in this assessment.

The hazard identification process enumerated a number of pest/pest groups associated with each port activity. An estimate of the economic consequences of each of these pests/pest groups is being developed to allow managers to balance port activities and the risks associated with each pest/pest group.

The objectives of the Fruit Fly Eradication Program Analysis are to assess the level of risk presented by each activity regulated by PPQ under fruit fly eradication programs, focussing on the regulated activities for a Medfly (*Ceratitis capitata*) infestation in Los Angeles County. The narrow scope of

this assessment should allow it to be accomplished within a short time frame. One of the unique elements of this assessment is that it will use relative values for the parameters evaluated.

Managers can use the results of this assessment to determine the most efficient use of program resources and to develop risk management guidelines for project leaders. After completion, a determination can be made on the benefits of expanding the scope to include other fruit fly species and locations.

## Risk Assessment Work in Support of Plant Protection and Quarantine Programs

By Richard Orr, Planning and Risk Analysis Systems Staff, Policy and Program Development

**How often do you do risk assessments?**

Approximately 30 percent of my time is spent on developing risk assessments and related methodologies. This varies with the specific projects I am working on.

**What methods or models do you use in completing risk assessments?**

Most of the assessments have been completed using the Generic Process, which involves a mixture of quantitative and qualitative methods. Combining the elements in the model is generally done qualitatively. The Generic Process model's individual elements, such as "spread potential" and "economics" are often quantified, while elements like "establishment potential" and "environmental damage" usually remain qualitative. Assessments that use the Enhanced Hazard Identification (EHI) approach are generally subjective in nature. The scenario tree analyses and the risk/mitigation matrix analyses are more quantitative than either the Generic or EHI approaches but still maintain a high degree of subjectivity (For examples, see respective processes in appendix 2, Plant Protection).

## Risk Analysis at the National Plant Germplasm Quarantine Center

By Arnold T. Tschanz, National Plant Germplasm Quarantine Center, Biological Assessment and Taxonomic Support Staff

**Why are you doing risk assessments?**

The National Plant Germplasm Quarantine Center is not the principal unit in the Biological Assessment and Taxonomic Support (BATS) staff doing Pest Risk Analysis (PRA). We do PRA's to develop, adapt, and/or approve new indexing protocols; recommend changes in the regulatory status of propagative plant material, principally genera prohibited or subjected to postentry quarantine; and determine features necessary for a quarantine facility.

**Why are you doing risk assessments?**

The National Plant Germplasm Quarantine Center is not the principal unit in the Biological Assessment and Taxonomic Support (BATS) staff doing PRA. We do PRA's to develop, adapt, and/or approve new indexing protocols; recommend changes in the regulatory status of propagative plant material, principally genera prohibited or
subjected to postentry quarantine; and determine features necessary for a quarantine facility.

**How often do you do risk assessments?**

We typically do frequent, short assessments.

**What methods or models do you use in completing risk assessments?**

We do not use a particular method, but rather analyze available quantitative and qualitative data.

**How are the risk assessments being used?**

PRA's are used in policy development, regulation change, new testing options for indexing protocols, and the initiation of a more extensive PRA.

**Do you have a list of risk assessments produced in your APHIS work?**

A list is not readily available. Examples of recent PRA's include: a quarantine facility workshop, regulation changes for strawberries and *Howea* (a palm genus), analysis of Rose Wilt for possible regulation change, analysis of Tomato Yellow Leaf Curl virus data to determine regulatory response, analysis of Plum Pox data to determine if regulatory change is necessary, evaluation of the sweet potato indexing protocol, and the development of a new rice treatment protocol.

# Wildlife Management

## Risk Assessments in Animal Damage Control

By Rick Wadleigh, Animal Damage Control (ADC), Operational Support Staff

**Why is ADC doing risk assessments?**

Animal Damage Control (ADC) conducts risk assessments as part of the compliance with National Environmental Protection Act (NEPA) and Endangered Species Act (ESA) regulations. The determination of when to do a risk assessment is generally established by these regulations. ADC is not a regulatory organization, so these risk assessments are not used to generate or review regulations. Rather, ADC is a service organization, devoted to helping resolve conflicts between wildlife and human objectives. Risk assessments are conducted to determine the probable impact of various wildlife control tools and strategies on the biological, economic, physical, and socio-cultural environment. For specific examples of risk assessments conducted by staff officers, see the following article by Alice Wywialowski.

In addition to these risk assessments focused on operational support of ADC programs, risk assessments are also incorporated into research and development activities of ADC. At least 50 percent of ADC's research budget is mandated for the development of non-lethal technologies. Risk assessments are used to evaluate the variety of hazards associated with applying new or different methods.

ADC also conducts risk assessments to support effective management of resources and staff time. Two common questions asked in management-based risk assessments are:

- Is this issue likely to result in a law suit against Animal and Plant Health Inspection Service (APHIS)?
- What are the risks of action versus no action?

The outcomes of these management support risk assessments are used to allocate physical, financial, and staff resources to competing ADC projects and programs.

**How often does ADC do risk assessments?**

Risk assessments are conducted continuously. The largest assessment completed to date took years and the efforts of many staff members and an independent contractor, while the smallest assessments are completed by one person with review by ADC staff. There are approximately six long assessments each fiscal year, with many more smaller assessments. About 10-15 risk assessments in support of operational programs are in progress at any one time during the year. Most typical assessments conducted as part of complying with NEPA regulations might require a month or more of work by a team composed of a Project Leader and two to three additional staff

members. The Project Leader may devote 60-75 percent of his or her time to the project, while the rest of the team typically devotes 10-30 percent of their professional time.

**What methods or models are used in completing risk assessments?**

ADC typically develops a model to represent each individual situation only if the risk assessment requires the development of such a model. Methods used in risk assessments include a decision table to compare the risks associated with a variety of potential actions in a given situation. This table may also be used to evaluate how well each program alternative answers issues that were raised in the public involvement phase of the risk assessment. Most assessments result in qualitative evaluations, which may be based on quantitative data where appropriate. Quantitative models are used to assess ADC program impact on wildlife population numbers, whereas issues such as "humaneness" are evaluated on a strictly qualitative basis.

**How are risk assessments being used?**

Risk assessments are being used to guide management decisions in day-to-day operations and allocation of resources, as well as supporting large scale programmatic decision making and research and development issues.

**How do you envision that risk assessment as a process will be used in APHIS 10-20 years from now?**

Within the next 10-20 years, ADC expects even greater demands for risk assessments, particularly to support compliance with NEPA and ESA documentation requirements. Within the next 5 years, methods are likely to stabilize and require an increased use of modelling.

**Do you have a list of risk assessments produced in you APHIS work?**

An APHIS-wide database of risk assessments completed for Environmental Impact Statements (EIS's) and Environmental Assessment Documents (EAD's) associated with NEPA is available through Biotechnology, Biologics, and Environmental Protection (BBEP)/Environmental Assessment and Documentation (EAD) Staff, Lauren Jones, at (301) 436-4829 [FAX (301) 436-5992]. For a list of risk assessments included in Endangered Species Consultations reports, contact ADC/Operational Support Staff at (301) 436-8281.

**Copies and citations of current risk assessments**

ADC released the final Environmental Impact Statement (EIS) for ADC Programs in April 1994. This three-volume EIS constitutes the largest risk assessment completed to date, and incorporates a description of risk assessment and risk management methods used in ADC programs. For the risk assessment, see U.S. Department of Agriculture (1994) volume 3, appendix P.

## Work in Risk Assessment for Animal Damage Control

By Alice Wywialowski, Planning and Risk Analysis Systems Staff, Policy and Program Development

**Why am I doing risk assessments?**

I have been doing primarily two types of risk assessments with the Animal Damage Control (ADC) program. The first type involves objective assessments to quantify the types and distribution of agricultural losses caused by wildlife. The goal of these assessments is to determine the distribution and magnitude of wildlife damage to agriculture. The second type of assessment more closely resembles other risk assessments completed within the Planning and Risk Analysis Systems (PRAS) staff. Of this type, I am working to complete an assessment for ADC to determine the best management strategy to exclude brown tree snakes from the United States. Most recently, I have been working with the U.S. Fish and Wildlife Service (FWS) to assess the potential risks and benefits of using black carp to control zebra mussels.

**How much of my work involves risk assessments?**

The ADC program has provided funds for the National Agricultural Statistics Service (NASS) to assess the magnitude of wildlife-caused losses to agriculture. In 1989, a nationwide project assessed the percentage of producers of different commodity types who believed that they sustained losses and the amount of their losses. In 1990, predator-caused losses of sheep and goats were assessed, and in 1991, predator-caused losses of cattle were assessed. In 1993, the amount of ripening field corn damaged by wildlife in the top 10 corn-producing states was objectively assessed. I have been extensively involved with the 1989 and 1993 assessments (Wywialowski 1994). The assessments have required a substantial portion (more than 50 percent) of my time while working for Animal and Plant Health Inspection Service (APHIS). These projects were broad in scope and took considerable time to complete.

**What methods or models have I used in my risk assessments?**

I select the methods that are most appropriate, given the information desired and the resources available to complete the job. The approach is as quantitative as possible given the information and resources available. For assessment of losses, we have worked cooperatively with the NASS. For the brown tree snake assessment, the assessment is based on a review of literature and conversations with individuals doing work related to the risk assessment. The black carp risk assessment will be completed primarily by FWS personnel with oversight and assistance from Richard Orr and myself.

**How are the risk assessments being used?**

The national assessment of wildlife-caused losses to agriculture has been used by the ADC program to describe the magnitude of the problem to the public. The information has been used in ADC program fact sheets and to respond to questions from the public. In addition, producers of products to alleviate problems have contacted me for additional information to determine the potential distribution and magnitude of the market for their products.

The 1989 national assessment was used as supporting information in describing the Affected Environment for the ADC Environmental Impact Statement. It has also been used by the ADC program to assess their allocation of program resources to address wildlife damage control management.

I anticipate the brown tree snake risk assessment will be used by the ADC program to determine the best use of their resources to reduce the risk of a brown tree snake introduction to Hawaii.

I anticipate the black carp risk assessment will be used by the FWS to determine the feasibility of using black carp to control zebra mussels.

**How do you envision that risk assessment as a process will be used in APHIS 10-20 years from now?**

The risk assessment process will become more refined in addressing problems of relevance to the agency. I anticipate that APHIS will have its roles more broadly defined and that we will work in closer cooperation with other agencies.

# Appendix 1
# Interview Questions

- Why are you doing risk assessments?

- How often do you do risk assessments? Are they many short ones, a few long ones, or in-between? What percentage of your work or that of your staff is devoted to doing risk assessments?

- What method(s) or model(s) do you use in completing risk assessments? That is, are they routinely based on one or two methods or does the method vary? Is the method chosen specifically for each particular problem or issue? Is the approach quantitative or qualitative, or a mixture of both?

- How are the risk assessments being used (i.e. policy guidance, immediate decision making, to develop options for program development etc.)?

- How do you envision that risk assessment as a process will be used in APHIS 10-20 years from now?

- Do you have a list of risk assessments produced in your Animal and Plant Health Inspection (APHIS) work? If so, would you be willing to share that list as a part of this information sharing? If so, please include.

- For risk assessments produced since FY 1990, please send two copies of each assessment. If this is not possible, please provide the full citation and location so that interested APHIS personnel can look at it. These documents will serve to build a centralized risk assessment collection within APHIS that can be shared.

- Please provide the name, address, telephone and FAX numbers for the person in your group who can be listed as a contact point for further discussion about your risk assessment activities.

# Appendix 2
# Risk Assessments in APHIS

Copies of risk assessments for APHIS programs are available through Policy and Program Development, Planning and Risk Analysis Systems by calling (301) 436-8252 until November 25, 1994. After that time, access can be gained by calling the APHIS Library at (301) 436-5240 and requesting a particular risk assessment by its Record Number.

**General or Methodology**

Ahl, A.S.; Acree, J.A.; Gipson, P.S.; McDowell, R.M.; Miller, L.; McElvaine, M.D. Standardization of nomenclature for animal health risk analysis. Risk analysis, animal health and trade. Rev. Sci. Tech. Off. Int. Epiz. 12(4):1045-1053; 1993. Record = U44

Ahl, A.S.; Orr, R. Assessment of plant pest and animal disease risk from importation and disposal of domestic garbage from Canada into United States landfills. [Hyattsville, MD]: Planning and Risk Analysis Systems, Policy and Program Development, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1991. Record = U48

Gay, C.G.; Orr, R.L. Risk analysis for veterinary biologics. [Hyattsville, MD]: Biotechnology Section, Veterinary Biologics; Biotechnology, Biologics, and Environmental Protection; Animal and Plant Health Inspection Service; U.S. Department of Agriculture; 1994. Record = U8

International approaches to plant pest risk analysis. Proceedings of the APHIS/NAPPO international workshop on the identification, assessment, and management of risks due to exotic agriculture pests; 1991 October 23-25; Alexandria, VA. NAPPO Bull. 11; 1993. Record = U70

Miller, L.; McElvaine, M.D.; McDowell, R.M.; Ahl, A.S. Developing a quantitative risk assessment process. Risk analysis, animal health and trade. Rev. Sci. Tech. Off. Int. Epiz. 12(4):1153-1164; 1993. Record = U42

Orr, R.; Cohen, S.D.; Griffin, R.L. Generic non-indigenous pest risk assessment process. Hyattsville, MD: Planning and Risk Analysis Systems, Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1993. (draft) Record = U46

Proceedings of the international seminar on animal import risk analysis; 1991 August 11; Carleton University, Ottawa, Canada. Acree, J.A.; Ahl, A.S., eds. Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Policy and Program Development; 1991. Record = U71

U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Policy and Program Development. Standards for pest risk analyses: plants in growing media. Quarantine 319.37 Nursery stock, plants, roots, bulbs, seed, and other plant products. [Hyattsville, MD]: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Policy and Program Development; 1990. Record = U87

**Animal Protection**

[Amen, J.] An assessment of the risk of a bluetongue virus introduction via the importation of bovine embryos from countries of high bluetongue prevalence. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; 1994]. Record = U35

[___]. An assessment of the risk of the introduction of foot and mouth disease via the importation of bovine embryos from foot and mouth disease infected nations. Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; [1994]. Record = U41

[___]. An estimate of the introduction of the FMD virus into the United States via fetal bovine serum of South American origin. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; 1994]. Record = U30

___. Analysis of the introduction and spread of *Mycobacterium bovis* via the importation of wallabies from New Zealand. Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; 1994. Record = U118

___. Evaluation of Aino virus and the importation of cattle from Japan. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export]; 1994. Record = U39

___. Evaluation of Ibaraki and the importation of cattle from Japan. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export]; 1994. Record = U40

___. Evaluation of the Akabane situation in Japan. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export]; 1994. Record = U38

___. Permanent post entry quarantine or release after one year. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export]; 1994. Record = U51

___. Probability of importing brushtail possums infected with *Mycobacterium bovis*. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; 1994]. Record = U32

___. Risk assessment on the introduction of *Elaphostrongylus cervi* via the importation of red deer from New Zealand. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export]; 1994. Record = U27

[___]. Risk assessment on the introduction of *Elaphostrongylus cervi rangiferi* via the importation of Norwegian reindeer. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; 1994]. Record = U29

___. The introduction, exposure, and spread of bovine brucellosis as a result of the importation of inbond heifers from Mexico. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export]; 1994. Record = U34

___. The probability of importing fetal bovine serum of South American origin through Central America. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; 1994]. Record = U31

___. The risk of the importation of tuberculous hedgehogs from New Zealand and the subsequent spread to humans and other animals. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; 1994]. Record = U33

___. The risk of the introduction of scrapie into the United States from South Africa via the importation of boer goats. [Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export]; 1994. Record = U37

Amen, J.; Butler, T.; Fite, R. Probability of VVND, HPAI, or SE4 in imported ostrich eggs. Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; 1994. Record = U28

Amen, J.; Malik, M.; Fite, R. Probability of FMD in imported ruminant serum from Argentina. Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export; 1994. Record = U36

Biotechnology Section, Veterinary Biologics; Biotechnology, Biologics, and Environmental Protection; Animal and Plant Health Inspection Service; U.S. Department of Agriculture. Biotechnology Analysis: rabies vaccine, vaccinia vector. [Hyattsville, MD]: Biotechnology Section, Veterinary Biologics; Biotechnology, Biologics, and Environmental Protection; Animal and Plant Health Inspection Service; U.S. Department of Agriculture; 1994a. Record = U11

___. Veterinary biologics risk analysis: Newcastle disease-fowl pox vaccine, fowl pox vector. [Hyattsville, MD]: Biotechnology Section, Veterinary Biologics; Biotechnology, Biologics, and Environmental Protection; Animal and Plant Health Inspection Service; U.S. Department of Agriculture; 1994b. Record = U9

___. Veterinary biologics risk assessment: rinderpest vaccine, vaccinia vector. [Hyattsville, MD]: Biotechnology Section, Veterinary Biologics; Biotechnology, Biologics, and Environmental Protection; Animal and Plant Health Inspection Service; U.S. Department of Agriculture; 1994c. Record = U10

Caplen, R.T. Benefit-cost analysis of the potential for establishment and spread of *Amblyomma variegatum* (tropical bont tick) and its associated diseases in the United States. Hyattsville, MD: Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1993a. Record = U74

Caplen, R.; McDowell, R.; Vollmerhausen, F.; Wilson, D. Puerto Rico tick eradication program – benefit-cost analysis. Hyattsville, MD: Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1992. Record = U110

Forsythe, K.; Corso, B. Welfare effects of the national pseudorabies eradication program: comment. Am. J. Agric. Econ. 6(4); 1994. In press. Record = U52

McElvaine, M.D.; McDowell, R.M.; Fite, R.W.; Miller, L. An assessment of the risk of foreign animal disease introduction into the United States of America through garbage from Alaskan cruise ships. Risk analysis, animal health and trade. Rev. Sci. Tech. Off. Int. Epiz. 12(4):1165-1174; 1993. Record = U43

Orr, R.L. A preliminary assessment of potential arthropod vectors of African horse sickness. Developed for APHIS VS by PPD. Hyattsville, MD: Planning and Risk Analysis Systems, Policy and Program Development,

Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1991. Record = U62

Rendleman, C. M.; Spinelli, F. J. An economic assessment of the costs and benefits of African swine fever prevention. Hyattsville, MD: Policy Analysis and Development, Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1994. Record = U114

Schoenbaum, M.A. Justification for reclassification of cattle on the September 10, 1993 tuberculin test of Williams dairy. [Memo]. 1993a September 22. Record = U82

___. Using a computer model to answer surveillance questions about pseudorabies. Pseudorabies epidemiology report. 5(4); December 1993b Record = U83

U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health. Qualitative analysis of BSE risk factors in the United States. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Animal Health Information; 1991. Record = U23 Contacts: Will Hueston; Kevin Walker

___. Quantitative risk assessment of BSE in the United States. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Animal Health Information; 1991. Record = U24 Contacts: Will Hueston; Kevin Walker

___. Assessment of risk factors for *Mycobacterium bovis* in the United States. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health; 1992. Record = U20 Contact: Kevin Walker

___. Michigan brucellosis importation risk assessment. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health; 1992. Record = U109 Contact: Michael Dalrymple.

___. A risk assessment of brucellosis vaccination. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health; 1993. Record = U108 Contact: Michael Dalrymple

___. A risk assessment of detecting disease, varying slaughter sample sizes. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health; 1993. Record = U106 Contact: Michael Brown; Kenneth Forsythe

___. Bovine spongiform encephalopathy: implications for the United States. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health; 1993. Record = U22 Contact: Kevin Walker

___. United States rendering and feed-manufacturing industries: evaluation of practices with risk potential for bovine spongiform encephalopathy. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health; 1993. Record = U25 Contact: Kevin Walker

___. Bovine spongiform encephalopathy risk preparedness. [Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health]; 1994. Record = U78 Contact: Kevin Walker

___. Calfhood vaccination risk assessment and costs: assessment of the effect of brucellosis calfhood vaccination on the risk of brucellosis with consideration of associated costs. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health; 1994. Record = U26 Contact: M.R. Dalrymple

___. *Escherichia coli* 0157:H7: issues and ramifications. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health; 1994. Record = U21 Contact: Kevin Walker

___. Foot-and-mouth disease risk analysis (part of the APHIS FMD Risk Analysis Working Group). [Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health]; 1994. Record = U85 Contacts: Randy Crom; Kelly Preston

___. Risk assessment of the practice of feeding recycled commodities to swine in the United States. Ft. Collins, CO: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health; 1994. Record = U105 Contact: Barbara Corso

**Environmental Protection**

U.S. Department of Agriculture; Animal and Plant Health Inspection Service; Biotechnology, Biologics, and Environmental Protection; and Syracuse Environmental Research Associates, Inc. Nontarget risk assessment for the Medfly cooperative eradication program. Hyattsville, MD: U.S. Department of Agriculture; Animal and Plant Health Inspection Service; Biotechnology, Biologics, and Environmental Protection; and Syracuse Environmental Research Associates, Inc. Record = U6

Vo, T.T.; Miller, C.E. An economic impact assessment of the Mediterranean fruit fly cooperative eradication program. Supporting document to the Environmental Impact Statement (EIS) for the Mediterranean Fruit Fly Cooperative Eradication Program. Hyattsville, MD: Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1993. Record = U115

**Plant Protection**

Caplen, R.T. Economic analysis of proposed 7 CFR part 319, Quarantine 40 regulations (Importation of logs, lumber, and other raw and processed wood products). Hyattsville, MD: Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1993b. Record = U111

Evangelou, P.; Kemere, P.; Miller, C.E. Potential economic impacts of an avocado weevil infestation in California. Hyattsville, MD: Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1993. Record = U112

Grimes, J. Economic impact of the establishment of Mexican fruit fly in the United States. Hyattsville, MD: Policy Analysis and Development, Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1992. Record = U88

Kemere, P. Potential losses of producer and consumer surplus from *Ipomoea aquatica* infestation of sugar cane and rice fields. Hyattsville, MD: Policy Analysis and Development, Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1993. Record = U113

Lakin, K.R. Assessment of the proposed release of *Scelio parvicornis* in the United States. Hyattsville, MD: Biological Assessment and Taxonomic Support, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1994. Record = U19

Miller, C.E. The Sharwil avocado risk analysis. Hyattsville, MD: Planning and Risk Analysis Systems, Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1991. Record = U16

___. Risk assessment: Mediterranean fruit fly. [Hyattsville, MD]: Planning and Risk Analysis Systems, Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1992. Record = U17

Orr, R. Importation of logs, lumber, and other unmanufactured articles: environmental impact statement. Hyattsville, MD: Planning and Risk Analysis Systems, Policy and Program Development, Animal and Plant

Health Inspection Service, U.S. Department of Agriculture; 1994. Record = U63

Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture. The cost of invading pests to U.S. agriculture. Hyattsville, MD: Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1993. Record = U89

## Generic Process

### *Commmodity Assessments*

Chile Pest Risk Assessment Team. Pest risk assessment of the importation of *Pinus radiata*, *Nothofagus dombeyi*, and *Laurelia philippiana* logs from Chile. U.S. Dep. Agric. For. Serv. Misc. Publ. 1517; 1993. Record = U66

New Zealand Log Pest Risk Assessment Team. Pest risk assessment of the importation of *Pinus radiata* and Douglas-fir logs from New Zealand. U.S. Dep. Agric. For. Serv. Misc. Publ. 1508; 1992. Record = U65

Orr, R.; Cohen, S. Q37 (plants in growing media) risk assessment implementation package. Draft USDA, APHIS, PPD report; ). 1991. Record = U90 Importation of plants established in growing media. Fed. Regist. 58:47074-47094 [docket no. 89-154]; 1993.

Redlin, S.C. Plant pathology pest risk assessment: New Zealand *Zea mays* seed. Hyattsville, MD: Biological Assessment and Taxonomic Support, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1992. Record = U12

Siberian Log Pest Risk Assessment Core Team. Pest risk assessment of the importation of larch from Siberia and the Soviet Far East. U.S. Dep. Agric. For. Serv. Misc. Publ. 1495; 1991. Record = U69

### *Specific Organism Assessment*

Chawkat, A.M. Pest risk assessment on cherry ermine moth (CEM) or hawthorn ermine moth (HEM) [*Yponomeuta padella*]. Hyattsville, MD: Biological Assessment and Taxonomic Support, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1994. Record = U18

Huettel, R.L.; Griffin, R.L.; Caplen, R.T. Pest risk analysis for pea cyst nematode, *Heterodera geottingiana*. Hyattsville, MD: Biological Assessment and Taxonomic Support, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1993. Record = U13

Lehtonen, P. Pest risk assessment on Chinese water spinach. USDA APHIS PPQ risk assessment. Hyatttsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Assessment and Taxonomic Support; 1993. Record = U72

___. Tropical soda apple risk assessment. Hyatttsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Assessment and Taxonomic Support; 1994. Record = U91

Orr, R.L. Pest risk assessment on apple ermine moth. Hyatttsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Assessment and Taxonomic Support; 1991. Record = U92

___. Pest risk assessment on cherry bark tortrix (CBT) [Enarmonia formosanus (Scopoli)]. Hyattsville, MD: Planning and Risk Analysis Systems, Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1991. Record = U59

Orr, R.L.; Cohen, S. Pest risk analysis on potato virus Y-N. [Hyattsville, MD: Planning and Risk Analysis Systems, Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture]; 1991. Record = U57

Schall, R.A. Pest risk analysis on Karnal bunt [*Tilletia indica*]. Hyattsville, MD: Port Operations, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1991. Record = U53

Schall, R.A.; Griffin, R. Pest risk analysis on larch-poplar rust, *Melampsora larici-populina*. Hyattsville, MD: Port Operations, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1992. Record = U14

Stewart, R.D. Characterizing and mitigating relative risk associated with the movement of tropical fruit fly host material into the United States for cold treatment at certain ports. [Hyattsville, MD]: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Assessment and Taxonomic Support; 1994. Record = U15

## Enhanced Hazard Identification Process

***As a Decision/Risk Process***

[Lorimer, N.; Orr, R.L.] Proposal for exotic forest pest list project (joint Canada, Mexicio, United States project). North American Forestry Commission. [1996]. In preparation. Record = U64

Orr, R.L. Risk assessment process for urgent and prompt interceptions. Developed for APHIS BATS by PPD [is being tested]. 1992. Record = U79

___. Pathway evaluation process. Aquatic Nuisance Species Task Force, Risk Assessment and Management Committee. Multiagency project. [1995]. In preparation. Record = U82

Orr, R.L.; Griffin, R. Proposed evaluation of non-indigenous weeds. Developed for APHIS BATS by PPD. Hyattsville, MD: Planning and Risk Analysis Systems, Policy and Program Development, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1993. Record = U60

***As a Commodity Assessment***

Orr, R.L. Pest assessment on Australian Riverland citrus. Draft developed for APHIS BATS by PPD. Maintained as draft because outside of review was not conducted. Hyattsville, MD: Biological Assessment and Taxonomic Support, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; 1992. Record = U61

## Scenario Tree Analysis

Ahl and Orr 1991. Referenced in General section. Record = U48

## Risk Mitigation Matrix Analyses

An efficacy review of control measures for potential pests of imported Soviet timber. U.S. Dep. Agric. APHIS Misc. Publ. 1496; 1991. Record = U68

Orr, R. Plant Protection and Quarantine requirement for the importation of *Pinus radiata* and Douglas-fir logs, lumber and wood chips from New Zealand. [Report results published in] Fed. Regist. 58:8524-8533 [Docket no. 91-074-4]; 1993. Record = U93

Reeves, D. Plant Protection and Quarantine requirements for the importation of *Pinus radiata* logs from Chile. [Report results published in] Fed. Regist. 58:8524-8533, Docket no. 91-074-4]; 1993. Record = U94

**Wildlife Management**

Butfiloski, J.W.; Hall, D.I. Environmental assessment: management of white-tailed deer-human wildlife conflicts at the Landings on Skidaway Island, Chatham County, Georgia. Hyattsville: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Damage Control; [1994]. Record = U5

Cohen, S.; Sterk, B.; Thomas, L.; Obrecht, H.; Pendleton, G. Deer survey on Federal land: a GIS application. Fish and Wildlife - Patuxent Wildlife Center; 1994. Record = 95

Risk Assessment and Management Committee. Aquatic Nuisance Species Task Force. Proposed generic non-indigenous aquatic organisms risk analysis review process (Draft). 1994. Record = U67

___. Nico, L. (National Biological Survey). Pest risk assessment on the introduction of triploid black carp as a biocontrol agent for zebra mussel. Funded by Fish and Wildlife Service. [December 1994]. In preparation. Record = U77

U.S. Department of Agriculture, Animal and Plant Health Inspection Service, and Forest Service, and U.S. Department of the Interior, Bureau of Land Management. Risk assessment of wildlife damage control methods used by the USDA, APHIS, Animal Damage Control program. Animal damage control program: final environmental impact statement. vol. 3, appendix P. Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Damage Control, Operational Support Staffs; 1994. Record = U1

Vo, T.T.; Evangelou, P. Economic consequences of the animal damage control program. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, and Forest Service, and U.S. Department of the Interior, Bureau of Land Management. Animal damage control program: final environmental impact statement. vol. 2, chapter 4. Hyattsville, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Damage Control, Operational Support Staffs; 1994. Record = U1

Wywialowski, A.P. Agricultural producers' perceptions of wildlife-caused losses. Wildlife Soc. Bull. 22(3):370-382; 1994. Record = U4

# Appendix 3
# Risk Assessment Contacts for APHIS Activities

**Animal Damage Control (ADC)**

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***Biotechnology***
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***Biological Assessment and Taxonomic Support (BATS)***
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Arnold T. Tschanz, Branch Chief, National Plant Germplasm Quarantine Center
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Lorene Chang, botanist
Sue Cohen, plant pathologist, geographic information systems
Richard Fite, veterinarian, poultry pathologist
Robert Griffin, plant pathologist
Charles Ed Miller, entomologist
Rob McDowell, biologist, agricultural economist
Michael McElvaine, veterinarian, epidemiologist
Alice Wywialowski, Senior Staff Wildlife Biologist
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**Regulatory Enforcement and Animal Care (REAC)**

***Animal Care***
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Room 554 Federal Building
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Hyattsville, MD 20782
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**Veterinary Services (VS)**

***Center for Epidemiology and Animal Health (CEAH)***
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